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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P O BOX 368 RIDGEFIELD, CT 06877			EXAMINER HUANG, EVELYN MEI	
			ART UNIT 1625	PAPER NUMBER

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/730,172

Applicant(s)

CYWIN ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-23 are pending.

Election/Restrictions

2. In response to the restriction requirement mailed on 8-10-2004, Applicant has elected the invention of Group I, claims 1-17 23, drawn to the compound of formula (I), the composition and the process of making. Claims 18-22 of Group II-IV inventions are withdrawn from further consideration as being drawn to the non-elected inventions.

Priority

3. This application is claimed to be a continuation of 10/453176.

However, new subject matter as recited in definition of R1 (f), and the definition of R6, and the species compounds in claims 6-16 are not described in 10/453176. This application is therefore a CIP and not a continuation of 10/453176.

Although a specific reference to the prior application(s) is found in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)), the relationship to 10/453176 is not described. The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-17, 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1,

- Line 1, 'compised of' should be 'comprised of'.
- Definition of R1, (g), (i), (j) 'optionally partially *of* fully halogenated' should be 'optionally partially *or* fully halogentated'
- The term 'ester' is not fully described in the specification and its full meaning is therefore not clear. Its deletion is recommended.
- The meaning of the term 'isomer' is unclear, as it embraces positional isomers, a description of which is not found in the specification. Recitation of the definition on page 55 of the specification is recommended.

b. The compound claims 2-5 are improperly dependent on the composition claim , because the compound does not further limit the composition. Amending these claims to the proper format for the compound claims is recommended.

c. Claims 2-5,

- It is unclear whether these claims are directed to a compound, or a mixture of the compound and the pharmaceutically acceptable salts thereof. It is recommended that the claim be written in the singular/alternative format, i.e. A compound of formula I,or a pharmaceutically acceptable salt thereof.
- The term 'ester' is not fully described in the specification and its full meaning is therefore not clear. Its deletion is recommended.
- The meaning of the term 'isomer' is unclear, as it embraces positional isomers, a description of which is not found in the specification. Recitation of the definition on page 55 of the specification is recommended.

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- d. Claims 3-5, definition of R1, (g), (i), (j) 'optionally partially *of* fully halogenated' should be 'optionally partially *or* fully halogenated'
- e. Claims 6-16,
- The term 'ester' is not fully described in the specification and its full meaning is therefore not clear. Its deletion is recommended.
 - The meaning of the term 'isomer' is unclear, as it embraces positional isomers, a description of which is not found in the specification. Recitation of the definition on page 55 of the specification is recommended.
- f. For the composition claim 17, it is unclear what is the 'therapeutically effective amount'. Therapeutically effective for what? Furthermore, 'compound of claim 1' is improper since claim 1 is directed to a composition.
- c. Claim 23, it is recommended that – of claim 4 – be inserted after 'a compound of formula (I)' to better define the claim.
- The rejection is applicable to claims dependent on the above claims.

Duplicate Claims

5. Claim 17 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

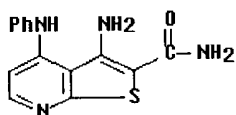
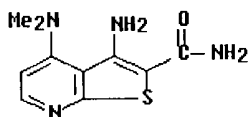
Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claims 1, 3, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kadushkin (Khimiko-Farmatsevticheskii Zhurnal (1992), 26(11-12): 62-6). The compounds of the following structures and the pharmaceutical composition thereof, are encompassed by the instant claims wherein R1 is NR₄R₅, and R2 is H.



8. Claims 1-4, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner (Pharmazie (1990) 45: 102-109, PTO-1449). The compounds B36-B40 (page 105, Table 2) and the pharmaceutical composition thereof, are encompassed by the instant claims wherein R1 is optionally substituted phenyl, and R2 is Cl-substituted phenyl or furanyl.

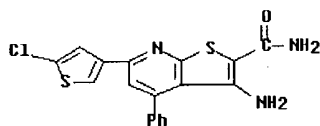
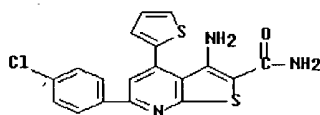
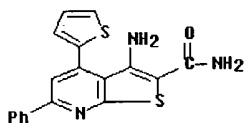
9. Claims 1-3, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Attaby (Phosphorus, Sulfur, and Silicone (1999), 149: 49-64, PTO-1449). The compounds 15 a, b (page 61) and the pharmaceutical composition thereof, are encompassed by the instant claims wherein R1 is phenyl or furanyl, and R2 is methyl.

10. Claims 3, 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Ghorab (Phosphorus, Sulfur, and Silicone (1998), 134/135: 447-462, PTO-1449). Compound 15 (page 262, Scheme 1) is encompassed by the instant claims wherein R1 is methyl, and R2 is phenyl.

11. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Kaigorodova (Chemistry of Heterocyclic Compounds (1996), 32(10): 1234-1238, PTO-1449). Compound Vc (page 295) is encompassed by the instant claim wherein R1 is methyl, and R2 is MeOCH₂.

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12. Claims 2, 3, 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Sharanin (Zhurnal Organicheskoi Khimii (1996), 32(8): 1251-1255). Compounds of the following structures are encompassed by the instant claims wherein R1 is thienyl or phenyl, and R2 is optionally substituted phenyl or thienyl.



Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1, 3, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arendsen (WO 00/75145, PTO-1449).

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Arendsen generically discloses an anti-inflammatory compound (pages 275-383, claim 1). A specific compound, 3-amino-4-(4-chlorophenoxy)thieno[2, 3-c]pyridine-2-carboxamide, is described on page 288, line 145.

Arendsen's compound is a thieno[2, 3-c]pyridine, whereas the instant is a thieno[2, 3-b]pyridine.

Arendsen, however, teaches that thieno[2, 3-c]pyridine and thieno[2, 3-b]pyridine are optional choices (page 275, lines 10-15). Specific thieno[2, 3-b]pyridine compounds are described (page 295, claim 9).

At the time of the invention, one of ordinary skill in the art would be motivated to replace Arendsen's a thieno[2, 3-c]pyridine with the alternative, exemplified thieno[2, 3-b]pyridine to arrive at the instant invention, with the reasonable expectation of obtaining an additional anti-inflammatory compound, since Arendsen had clearly taught that any species within the disclosed genus, especially the exemplified compounds, would be effective as an anti-inflammatory agent.

15. Claims 1, 3, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner (PTO-1449).

Wagner discloses an anti-allergic compound (page 105, compound B/43).

Wagner's compound has a $-C(O)NH_2$, whereas the instant compound has a $-C(O)NHCH_3$ as R1.

The instant aminomethyl is the next adjacent homolog of Wagner's amino hydrogen. The alkylation of the amino nitrogen is an obvious modification, as exemplified in compound B/44 (page 105).

At the time of the invention, the skilled artisan would expect these compounds to have similar activities in view of their close structural relationship. One of ordinary skill in the art would be motivated to replace Wagner's $-C(O)NH_2$, with the homologous $-C(O)NHCH_3$ to arrive at the instant invention, with the reasonable expectation of obtaining an additional anti-allergic compound.

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Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17, 23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8, 14 of copending Application No. 10/453175. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending compound, especially the species compound of copending claim 6, the composition, and process of making thereof, are encompassed by the instant generic claims. The composition comprising the species as recited in instant claims 6-16 is obvious over the composition comprising the species compound of the copending claim 6.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

17. The compound wherein R2 is a heterocyclyl as defined in claims 3-5, and the composition thereof, and the process of making thereof, would be allowable upon overcoming the 112 second paragraph rejection and the provisional obviousness type double patenting rejection.

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Kadushkin's compound as a hydrogen, whereas the instant has a heterocyclyl as R2.

Motivation to modify Kadushkin's compound to arrive at the instant is lacking.

While Arendsen generically teaches that R2 may be heterocyclyl, an example wherein R2 is heterocyclyl has not been described. Furthermore, the closest example compound (page 288, line 145) is a thieno[2, 3-c]pyridine, whereas the instant is a thieno[2, 3-b]pyridine. Motivation to modify Arendsen's compound via multiple changes to arrive at the instant invention is lacking.

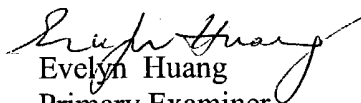
Wagner's compound has a methyl, whereas the instant has a heterocyclyl as R2.

Motivation to modify Wagner's compound to arrive at the instant is lacking.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang
Primary Examiner
Art Unit 1625